IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL ACTIVE PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**[1]	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE, OR IN THE ALTERNATIVE, TO LIMIT THE OPINIONS AND TESTIMONY OF OLGA RAMM, M.D.

Dr. Ramm is an accomplished obstetrician and gynecologist who is board certified in Female Pelvic Medicine & Reconstructive Surgery. She is the Regional Chief of Female Pelvic Medicine and Reconstructive Surgery for Kaiser Permanente Medical Group, Northern California and has performed approximately 1,400 TVT implant surgeries. She has authored and co-authored many articles in peer-reviewed publications, teaches medical students and residents, and has given a multitude of presentations to various professional organizations and groups. And she has received several honors and awards for her surgical teaching.

Dr. Ramm is therefore well qualified to offer opinion testimony, which is supported not only by her substantial clinical experience and teaching background, but also by high-quality scientific evidence. Her opinions are thus based on "good grounds" and will assist the trier of fact to understand the evidence and determine facts in issue—namely, whether the TVT mesh

[1] Plaintiffs list four cases to which their motion applies, but only two of those cases are still active in this litigation—*Galarza* and *Moore*.

product is defective and whether Plaintiffs can meet their burden of establishing general and specific causation.

As more fully explained below, Defendants Ethicon, Inc., Ethicon LLC, and Johnson and Johnson (Ethicon) respectfully request that the Court deny Plaintiffs' motion to exclude Dr. Ramm's testimony.

ARGUMENTS AND AUTHORITIES

I. Dr. Ramm is qualified to testify about risks that are within the common knowledge of physicians.

Plaintiffs claim, without support, that Dr. Ramm offers opinions about the "adequacy" of the TVT IFU and claim she is unqualified to do so because she has never drafted an IFU. Pls.' Mem. (Dkt. 3616) at 2-3. They alternatively argue that Dr. Ramm's "adequacy" opinion is unreliable because it is not based on a review of all IFUs.

Plaintiffs, however, point to no opinions where Dr. Ramm offers an adequacy opinion, nor has she done so. On the contrary, the opinions Plaintiffs challenge have nothing to do with the adequacy of the IFU. Instead, Dr. Ramm opines that the risks Plaintiffs' experts claim should be included "are not true risks" but "are risks that are common to stress urinary incontinence and vaginal surgery and are basic risks that are fundamental knowledge in the field." Ex. B to Pls.' Mot. (Dkt. 3614-2), Ramm Report at 53-54. This opinion is grounded in the scientific method, the law, within her expertise, and consistent with the Court's Wave 1 rulings. Indeed, this Court has expressed "no opinion" about "whether certain risks were common knowledge," and therefore has not precluded this expert testimony. *See, e.g.*, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016).

And Dr. Ramm is well qualified to offer opinions about "basic risks that are fundamental knowledge in the field." Ex. B to Pls.' Mot. (Dkt. 3614-2), Ramm Report at 53-54. As Director

of the Female Pelvic Medicine and Reconstructive Surgery Fellowship Training Program, she is knowledgeable about the required training curriculum for residents and fellows in this program. *Id.* at 2. She has given lectures to educate residents and fellows "about the indications, relative contraindications, expected outcomes, safety, and efficacy of the surgical and non-surgical treatment options for stress urinary incontinence" and has taught residents and fellows how to perform the TVT procedure in the operating room. *Id.* And she has received several honors and awards for doing so. *Id.* Moreover, as Chief of Female Pelvic Medicine and Reconstructive Surgery, she is a recognized specialist in female pelvic medicine and reconstructive surgery; she has performed approximately 1,400 TVT implant surgeries over the course of her career and has published peer-reviewed articles in the area of pelvic-floor medicine. *Id.* at 1-2; *see also* Ex. C to Pls.' Mot. (Dkt. 3614-3), Ramm Curriculum Vitae at 3.

Consistent with this background, Dr. Ramm is well aware of what risks are within the common knowledge of pelvic-floor surgeons because not only is she an experienced pelvic-floor specialist, but she also teaches those risks to residents and fellows in this area of medicine. Ex. B to Pls.' Mot. (Dkt. 3614-2), Ramm Report at 2. In her opinion, pelvic surgeons are educated and trained on the multitude of potential risks of pelvic-floor surgery that are listed in her report, including bleeding events (hemorrhage, hematoma, and the need for transfusion), organ injury (bladder, lower urinary tract, nerves, and vessels), voiding dysfunction (frequency, interrupted voiding, and hesitancy), retention, detrusor instability (urgency and frequency), infection, wound complications, vaginal and pelvic pain, dyspareunia, inflammation, fistula, scarring, and revisions, among other risks, and can be acute or chronic. *Id.* at 54. In her opinion, "[m]esh exposure and erosion are the only unique risks with the use of TVT." *Id.*

As an experienced pelvic-floor surgeon, she need not be familiar with FDA rules or regulations to give this testimony. *See United States v. Articles of Device*, 426 F. Supp. 366, 370 (W.D. Pa. 1977) (allowing FDA to offer evidence by affidavits of two medical experts as to what information is within common knowledge of physicians in a misbranding case); *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *6-7, 15 (S.D.W. Va. Apr. 24, 2015) (discounting Dr. Galloway's unfamiliarity with FDA regulations and requirements for warnings); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703-04, 719 (S.D.W. Va. 2014) (finding Drs. Rosenzweig and Blaivas adequately experienced physicians to testify about risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *13-14 (S.D.W. Va. May 19, 2016) (finding Dr. Shull qualified to testify "on the completeness and accuracy of the [mesh product's] warnings from a clinical perspective" because his testimony did not touch on regulatory issues). Indeed, a physician is qualified to make a comparison between "the risks [the physician] perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Id*. This principle is consistent with the rulings this Court recently issued for Wave 1 cases—namely, that a urogynecologist is qualified to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 (S.D.W. Va. Aug. 31, 2016).

Moreover, her opinions on this issue are consistent with the legal principle that Ethicon, like other medical device manufacturers, has no duty to warn pelvic-floor surgeons of risks commonly known to attend pelvic-floor surgery. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (instructing that the duty to warn is of dangers "not well known to the

medical community"); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2015 WL 4944339, at *7 (S.D.W. Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about 'risks already known to the medical community.'"). As stated generally in the Restatement (Third) of Torts: Products Liability § 2 cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF TORTS §§ 388(b), 402A cmt. j. In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings, and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added).

Based on this support, Dr. Ramm is qualified to offer the opinion that Plaintiffs really challenge—*i.e.*, that the risks Plaintiffs' experts claim should be included in the IFU "are not true risks" but "are risks that are common to stress urinary incontinence and vaginal surgery and are basic risks that are fundamental knowledge in the field." Ex. B to Pls.' Mot. (Dkt. 3614-2), Ramm Report at 53-54. As Chief of Female Pelvic Medicine and Reconstructive Surgery and a practicing surgeon who went through years of medical education and training, she has extensive clinical experience with pelvic-floor surgeries, publishes in peer-reviewed publications, and directs the training program for fellows and residents, Dr. Ramm is uniquely qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic-floor surgeries.

It is of no consequence then that Dr. Ramm has never drafted an IFU, or offered input to a medical device manufacturer about information to be included in an IFU, because she is not offering an opinion that the TVT IFU is adequate as Plaintiffs claim. Indeed, Ethicon is mindful

of the Court's Wave 1 ruling that experts without additional regulatory expertise on product labeling and compliance cannot testify "about what an IFU should or should not include." *See, e.g.*, *In re: Ethicon Inc.*, 2016 WL 4557036, at *3. Dr. Ramm will not be offering opinions about what should or should not be included in an IFU. Ethicon respectfully submits, however, that risks that are within the common knowledge of physicians are risks that would not, as a matter of logic, be included in an IFU. This logical result, however, does not mean that an expert's common-knowledge testimony should be excluded under the Court's exclusionary "additional expertise" directive. Instead, the Court's directive goes to the lack of expertise in regulatory requirements and compliance, not whether a particular risk is within the common knowledge of physicians. *See Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015) (distinguishing between an expert's expertise "in the requirements for product labeling" and the expert's qualifications as a practicing physician to testify about risks provided in the text of the product's labeling).

In accordance with this distinction and the Court's limitations, Dr. Ramm will not testify about the regulatory requirements for product labeling for the IFUs at issue here or what the IFU should or should not include. But she is qualified by education, training, and experience to give opinions about what risks are within the common knowledge of surgeons who perform pelvic-floor surgery. Any disagreement Plaintiffs may have with Dr. Ramm's opinions on this issue goes to weight, not admissibility.

There should be no different result with respect to Plaintiffs' alternative "reliability" argument as well. That argument is premised on Plaintiffs' misperception that Dr. Ramm is offering a warnings adequacy opinion when she is not.

II. Dr. Ramm—an experienced pelvic-floor surgeon—need not be an engineer to opine about mesh properties.

Plaintiffs claim that Dr. Ramm's opinions about mesh properties—including degradation porosity, inertness, weight, and cut—are "design" opinions that she is not qualified to offer because she is not a materials engineer, has never designed a mesh product, and has never examined explanted mesh under an electron microscope. Pls.' Mem. (Dkt. 3616) at 3-4. Plaintiffs' argument fails for two reasons.

A. An engineering degree is not required.

This Court has repeatedly instructed that an expert need not be a materials engineer or designed a mesh product to offer opinions about various mesh properties. *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493535, at *3 (S.D.W. Va. Aug. 25, 2016) (rejecting plaintiffs' argument that Dr. Bales's is unqualified to offer opinions about whether mesh degrades because he is not an engineer); *see also In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582210, at *4 (S.D.W. Va. Sept. 1, 2016) (rejecting plaintiffs' argument that Dr. Horbach is not qualified to offer opinions about mesh properties because she never designed a mesh product). Instead, an expert with extensive clinical experience in urogynecology who has reviewed the relevant literature—as Dr. Ramm did here—is qualified to give opinions about mesh properties. *In re: Ethicon Inc.*, 2016 WL 4493535, at *3; *In re: Ethicon Inc.*, 2016 WL 4582210, at *4.

Nor does Dr. Ramm need to be an expert in engineering to give opinions about mechanical- versus laser-cut mesh. Like Dr. Kenton in *In re: Ethicon Inc. Pelvic Repair Systems Product Liability Litigation*, MDL No. 2327, 2016 WL 4945099, at *2-3 (S.D.W. Va. Aug. 31, 2016), Dr. Ramm has used both mechanical-cut and laser-cut mesh (Ex. 1, 3/17/17 Ramm Dep. Tr. 38:14-39:1), which makes her qualified to offer opinions about the clinical differences

between those two cuts of mesh even though she is not an engineer. *See also In re: Ethicon Inc.*, 2016 WL 4945099, at *2-3 (rejecting plaintiffs' argument that Dr. Kenton is unqualified to offer opinions about the clinical differences between because she is not an engineer).

The same holds true for Dr. Ramm's opinions about porosity and weight, or any other mesh property. Dr. Ramm need not be an engineer to give these opinions and she need not have analyzed mesh microscopically. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4944702, at *3 (S.D.W. Va. Aug. 30, 2016) (rejecting plaintiffs' argument that Dr. Schwartz is unqualified to offer opinions about pore size, among other mesh properties opinions, because he is not an engineer and never analyzed explanted mesh under a microscope). Instead, an expert with extensive clinical experience, as Dr. Ramm has here, qualifies her to opine about the mesh's reaction to and effect on the human body. *Id.*; *see also In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536875, at *3 (S.D.W. Va. Aug. 30, 2016) (rejecting plaintiffs' argument that Dr. Serels is not qualified to offer various mesh properties opinions because he is not an engineer or pathologist); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493364, at *2-3 (S.D.W. Va. Aug. 25, 2016) (rejecting plaintiffs' argument that Dr. Toglia is not qualified to offer opinions about polypropylene safety and mesh weight because he is not an engineer).

It makes no difference then that Dr. Ramm is not a materials engineer, that she has never designed a mesh product, or that she has not examined explanted mesh under an electron microscope. Her extensive clinical experience and review of the literature qualifies her to opine about the TVT mesh's clinical effect on the human body as well as the safety and efficacy of mesh products.

B. Dr. Ramm is not offering opinions about the process of designing a product.

Plaintiffs' design argument fails for a second reason as well. Dr. Ramm is not offering opinions about the *process* of designing a product that would require engineering or product design expertise. On the contrary, she is offering opinions about the clinical effects of various mesh properties on the human body based on her extensive clinical experience with the TVT mesh product. Ex. B to Pls.' Mot. (Dkt. 3614-2), Ramm Report at 33-53.

As this Court has said repeatedly, an expert's "mere utterance" of the word "design" does not transform the expert's opinion into a design opinion. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493585, at *3 (S.D.W. Va. Aug. 25, 2016). It is only when the expert offers opinions "about the process of designing a product" that the expert can be considered to have offered a design opinion. *Id*. (rejecting plaintiffs' argument to exclude Dr. Anhalt's "design" opinion because he did not offer any opinions about the process of designing a product); *see also, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4547053, at *3 (S.D.W. Va. Aug. 31, 2016) (same as to Dr. Grier); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Elser); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4958312, at *3-4 (S.D.W. Va. Aug. 25, 2016) (same as to Dr. Carbone), among others.

Like Drs. Anhalt, Grier, Elser, and Carbone, in these cases, Dr. Ramm offers no opinions about the *process* of designing a product. Plaintiffs' criticisms about her lack of product design experience should be rejected.

CONCLUSION

For the foregoing reasons, Ethicon respectfully asks this Court to deny Plaintiffs' motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 27, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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